ALABAMA MEDICAID AGENCY
PREFERRED DRUG PROGRAM
PHARMACY AND THERAPEUTICS COMMITTEE
OPERATING PROCEDURES

Public Notice

Medicaid will provide notice to the public of Pharmacy and Therapeutics (P&T) Committee meetings and agenda items not less than (30) calendar days in advance of scheduled meetings. The notice will be provided via the Medicaid web site.

Medicaid will send written notification not less than (30) calendar days prior to a meeting of the P&T Committee to pharmaceutical manufacturers whose brand name drug(s) may be considered for preferred status at said meeting. This notice will be provided via US Certified Mail and the Medicaid web site. If an issue arises during a clinical review conducted by the P&T Committee that requires follow-up consideration at the next P&T Committee meeting, a minimum of thirty (30) days notice will be given to affected manufacturers.

Medicaid will maintain a database of industry representatives for the purpose of correspondence and notice regarding the Preferred Drug Program. It is the responsibility of the manufacturer to provide accurate contact information to the Medicaid Pharmacy Director delegated representative and to provide update information as needed. Contact information is to be provided on the Pharmaceutical Manufacturer Contact Information Form located on the Medicaid web site. It is also available from the Medicaid Pharmacy Program Office at (334) 242-5050. In the event no contact information is provided to Medicaid, the Legal Contact on file with the Medicaid Drug Rebate Program will be utilized for notices.

Request For Product Review

Manufacturers may request a product review for a new pharmaceutical product falling within the scope of the Preferred Drug Program.

a. Requests for product reviews must be submitted in writing and directed to the Medicaid Pharmacy Director or delegated representative.

b. Requests for product reviews of drugs will be considered in the order in which they are received unless Medicaid identifies a need to place a higher priority on a particular class/drug.

c. A product or a product with a new indication must have been on the market for a minimum of six (6) months prior to a request for product review.

Manufacturers may submit written evidence supporting inclusion of a product on the Preferred Drug List to the Medicaid Pharmacy Clinical Support Personnel or delegated representative and should be clearly labeled as a request for product review. This information may be submitted to Medicaid or its delegated representative at any time. However, the scheduling of the product's review will be at Medicaid's discretion.

Manufacturer Comment

Manufacturers have the opportunity to present comments to the Medicaid P&T Committee as required by Act No. 2003-297 through written comments directed to the Medicaid Pharmacy Director or delegated representative.

a. Comment period is for a period of 21 calendar days prior to the Pharmacy and Therapeutics Committee meeting. If the deadline falls on a weekend or holiday, comments must be received by noon CST of the next business day.

b. All manufacturer comments received and approved by the deadline will be included in the review packet provided to the P&T Committee members. Manufacturer comments are to be clinically based and are not to contain any reference to cost information. Any comments found to contain references to cost information will be rejected in their entirety.

c. Manufacturer comments should be clearly labeled as such and should indicate the product and drug class the comments represent. It is the responsibility of the manufacturer to provide twenty (20) copies of the written comments by the deadline.

Oral Presentations

Manufacturers have the opportunity to make oral presentations to the Medicaid P&T Committee through a brief oral summary of their product.

a. Oral Presentations will be restricted to products that are being reviewed for preferred status.

b. Written submission of a one page summary of the material to be presented at the P&T meeting must be received by the Medicaid Pharmacy Director or delegated representative a minimum of 21 calendar days prior to the scheduled P&T meeting. The summary must include all major points to be made during the presentation and a complete summary of the information to be shared at the meeting. The oral presentation summary should be clearly labeled as such. If the summary is not received by the deadline stated, an oral presentation will not be permitted at the meeting. It is the responsibility of the manufacturer to verify receipt by Medicaid. If the deadline falls on a weekend or holiday, the summary must be received by noon CST of the next business day. If the deadline falls on a business day, the summary must be received by 5:00 p.m. CST.

c. Presenters must register with Medicaid at P&T meetings a minimum of ten (10) minutes prior to the scheduled start time of the meeting. A sign-in sheet will be provided at a registration table at the meeting location. Those not registered by the designated cut off time will not be allowed to make presentations.

d. Presentations will be limited to a maximum of five (5) minutes per representative per drug class.

e. Presentations will be limited to one representative per company per drug class. Only one presentation per product will be permitted.

f. Representatives will be called to present in the order in which they signed in by drug class.

g. Representatives will be responsible for providing twenty (20) copies of the one-page presentation summary if they wish to have it distributed to P&T Committee members at the meeting. All copies must be submitted to Medicaid at the time of sign-in prior to meeting. Medicaid personnel will distribute the copies to the members.

h. Presentations must be limited to verbal comments. No visual aids other than designated handouts are permitted.

i. Presentations must be limited to comments regarding the branded products within the class being considered for preferred status at the current meeting.

j. Presentations are to be limited to clinical issues. No cost information is to be presented either verbally or in the designated handouts. Presenters will be stopped if cost information is presented. Oral presentations should follow the one page summary that was submitted to Medicaid.

k. The Chairman will call for presentations by drug class. The oral presentation period will be closed just prior to the clinical review presentation of each drug class. Medicaid's Contractor will then present clinical reviews by class. The Committee will then hold discussion and vote by ballot. No discussion will be permitted during presentations by the manufacturers. Dialogue between the Committee and a representative will only occur if called for by the Chairman.

l. Oral Presentations will be allowed subject to time constraints at the discretion of the Chairman or the Medicaid Commissioner so that the P&T Committee's ability to complete the planned agenda is not impeded.

Meeting Attendance

Attendees of meetings are to limit distractions to a strict minimum. Cellular telephones and pagers must be turned off or to silent mode before entering the meeting room.

All attendees of the P&T Committee meetings are to sign-in at the registration table.

Public Information

P&T Committee review packets will be posted to the Medicaid web site by noon of the day of the P&T meeting. The review packets will not be available for purchase at the sign-in table.

All manufacturer comments received and approved during the comment period will be included in the review packet for the P&T Committee meeting.

Medicaid shall post the PDL decisions to the Medicaid web site on the 10th business day following the date of the P&T Committee meeting.

Notice of prior authorization will be posted to the Medicaid web site a minimum of two weeks prior to the implementation of the PA. In addition, the prior authorization request form and criteria will also be posted with this notice.

Reconsideration Process

Manufacturers may request a reconsideration of a clinical recommendation of the P&T Committee. Written request must be submitted to the Medicaid Pharmacy Director and must be received within thirty (30) calendar days of the posting of the PDL decisions to the Medicaid web site.

Request must include clinical documentation including references to justify reconsideration. Manufacturer contact information should also be included with the submission.

Medicaid will respond in writing to all appeals within ninety (90) calendar days of receipt. Responses will be sent via US Certified Mail.

General

Medicaid staff reserves the right to delete agenda items if they deem it necessary due to time constraints of the meeting.

CONTACT INFORMATION:

Alabama Medicaid Agency
Bakeba R. Thomas, Administrator
Pharmacy Clinical Support Unit
501 Dexter Avenue
P. O. Box 5624
Montgomery, AL 36103-5624
Telephone: (334) 242-5050
Fax: (334) 353-7014
Email: Bakeba.Thomas@medicaid.alabama.gov
Medicaid web site: www.medicaid.alabama.gov